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Zhao et al.

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(54) **MRI COMPATIBLE IMPLANTABLE MEDICAL LEAD AND METHOD OF MAKING SAME**

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A61N 1/05 (2006.01)
A61N 1/08 (2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/056*** (2013.01); *A61N 2001/086* (2013.01)

(58) **Field of Classification Search**

CPC A61N 1/05; A61N 1/056; A61N 2001/086
USPC 607/115, 116, 119, 122
See application file for complete search history.

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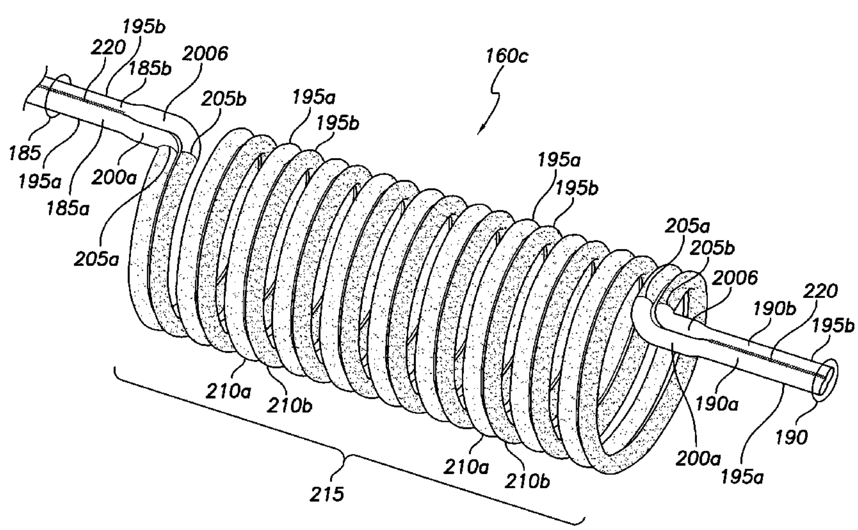
Primary Examiner — Mallika D Fairchild

(57) **ABSTRACT**

An implantable medical lead is disclosed herein. The lead may include a body and an electrical pathway. The body may include a distal portion with an electrode and a proximal portion with a lead connector end. The electrical pathway may extend between the electrode and lead connector end and may include a coiled inductor including first and second electrically conductive filar cores. The first and second filar cores may be physically joined into a unified single piece proximal terminal on a proximal end of the coiled inductor. The first and second cores may be physically joined into a unified single piece distal terminal on a distal end of the coiled inductor. The first and second filar cores may be helically wound into a coiled portion between the proximal and distal terminals, the filar cores being electrically isolated from each other in the coiled portion. The proximal terminal may be electrically coupled to a portion of the electrical pathway extending to the lead connector end, and the distal terminal may be electrically coupled to a portion of the electrical pathway extending to the electrode.

27 Claims, 8 Drawing Sheets



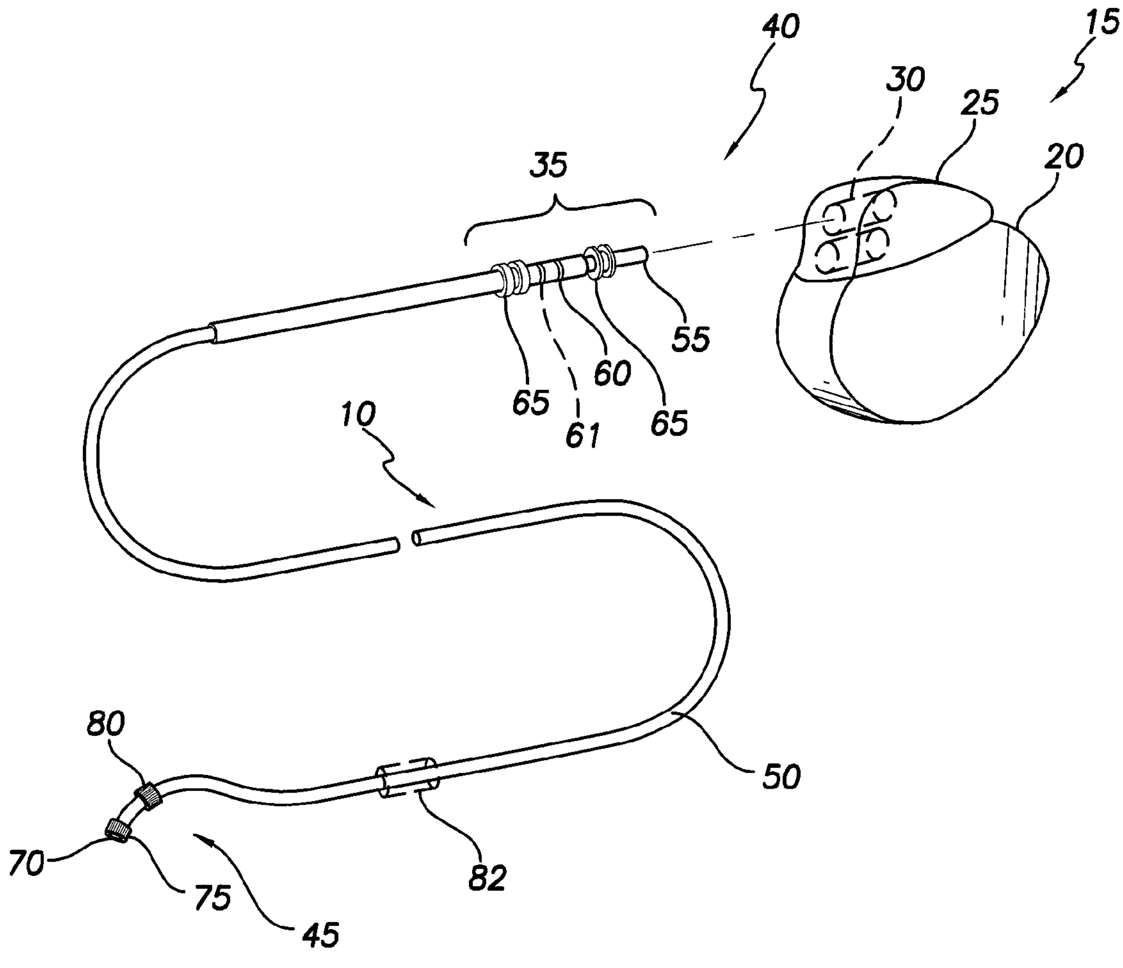
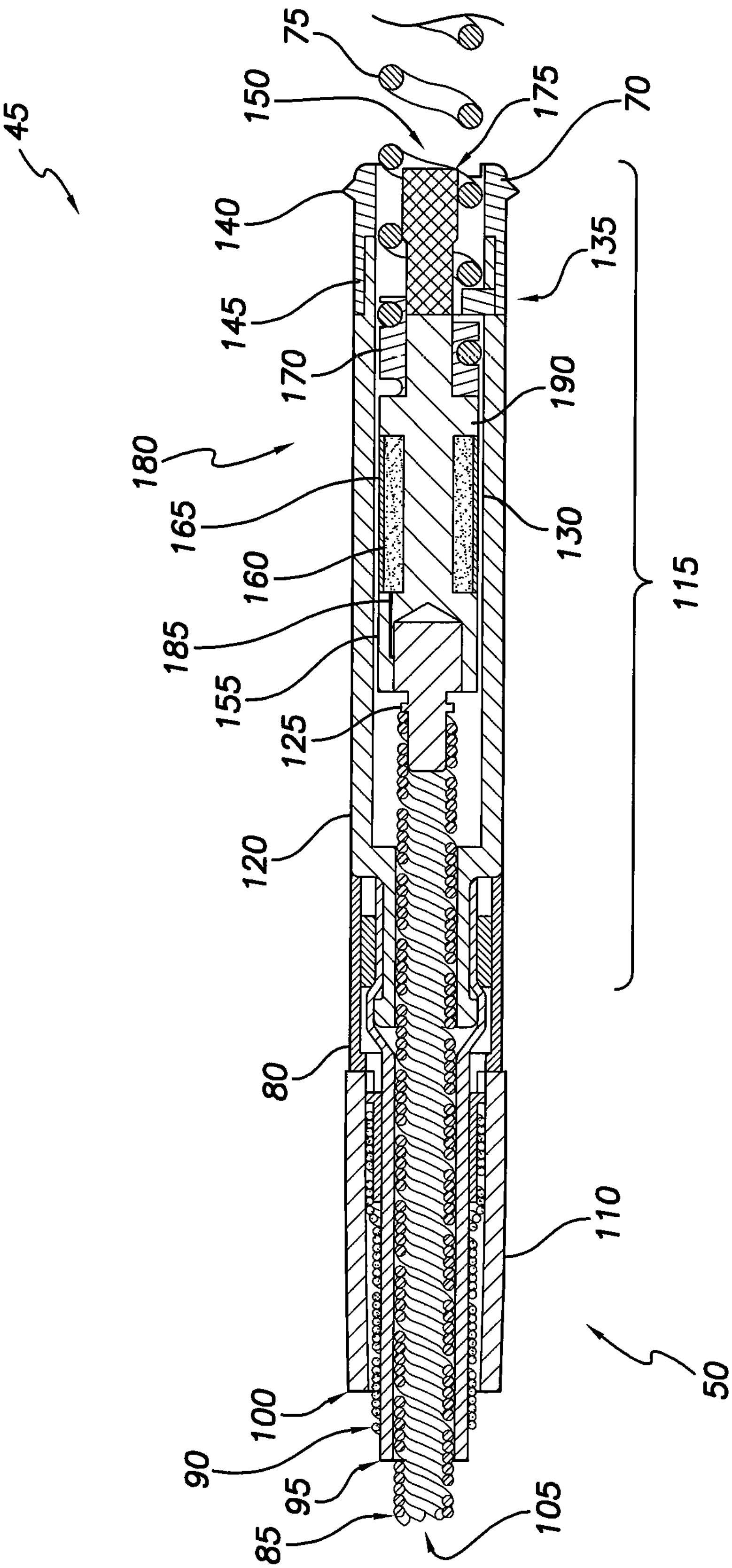


FIG. 1



45
75
150
175
70
140
135
145
170
190
180
165
130
160
115
185
155
125
120
80
110
50
100
90
95
105
85

FIG. 2

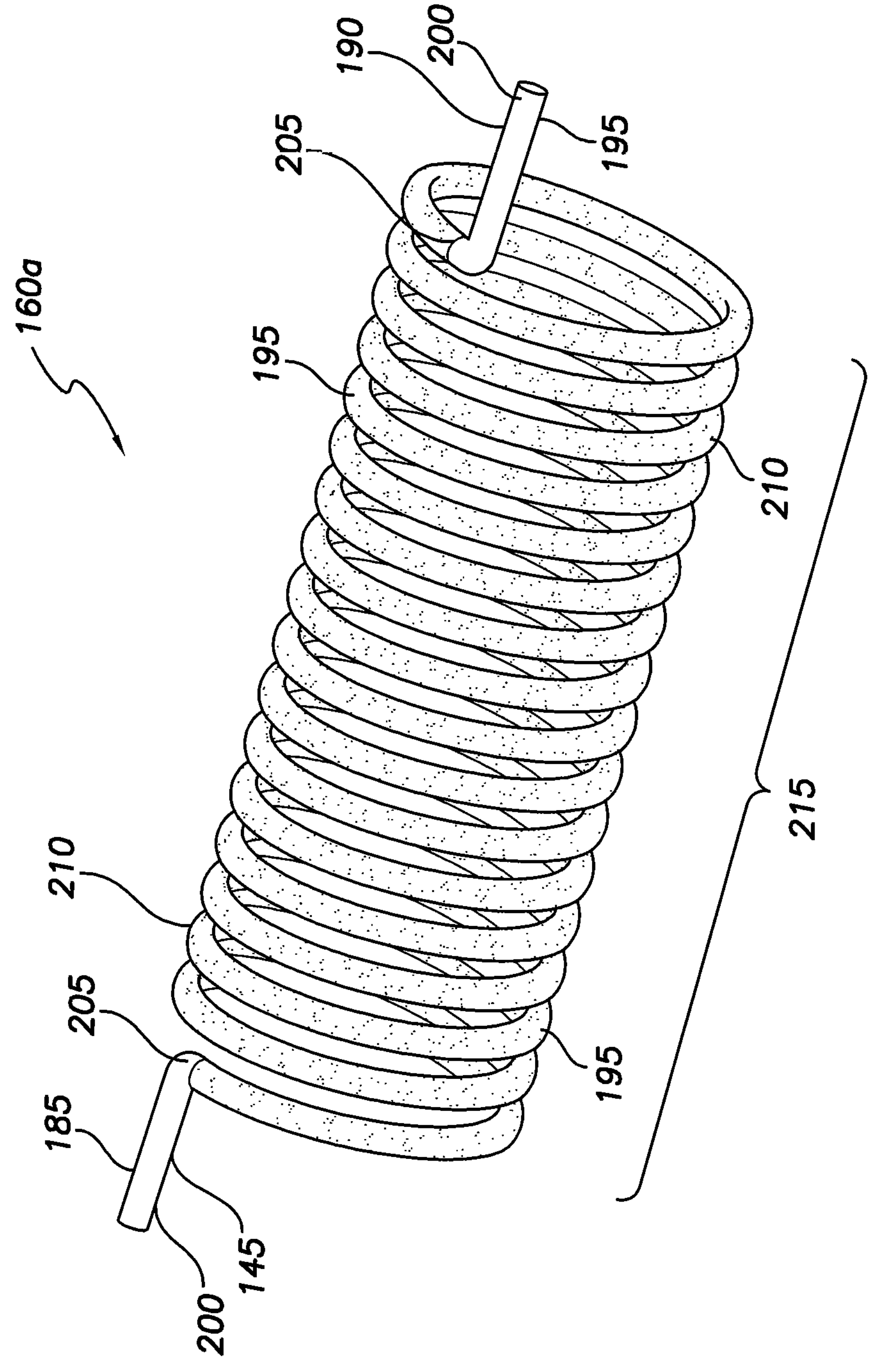
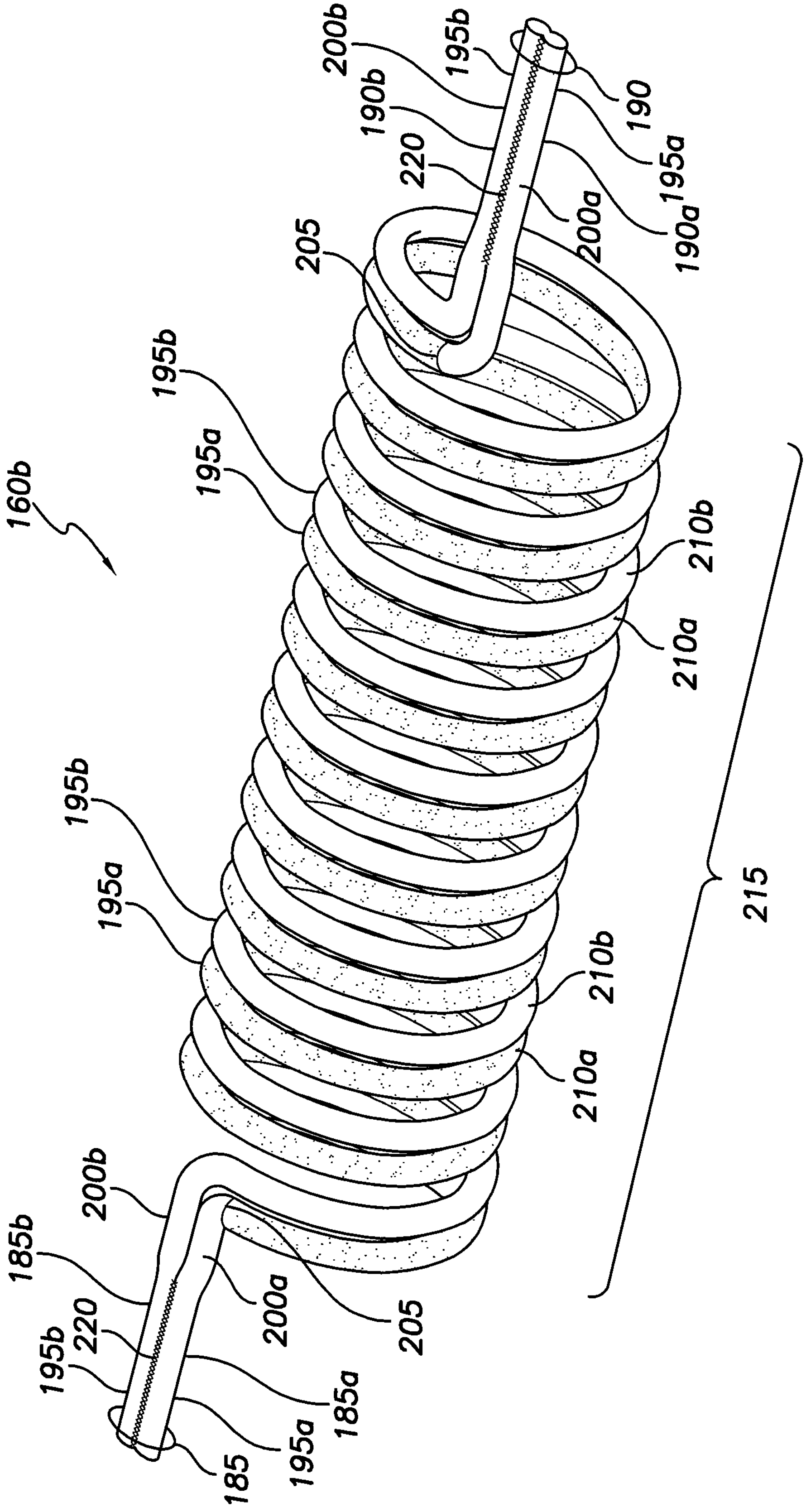


FIG. 3



160b
200b
195b
190
190b
195a
220
200a
190a
205
195b
195a
210b
210a
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210a
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200b
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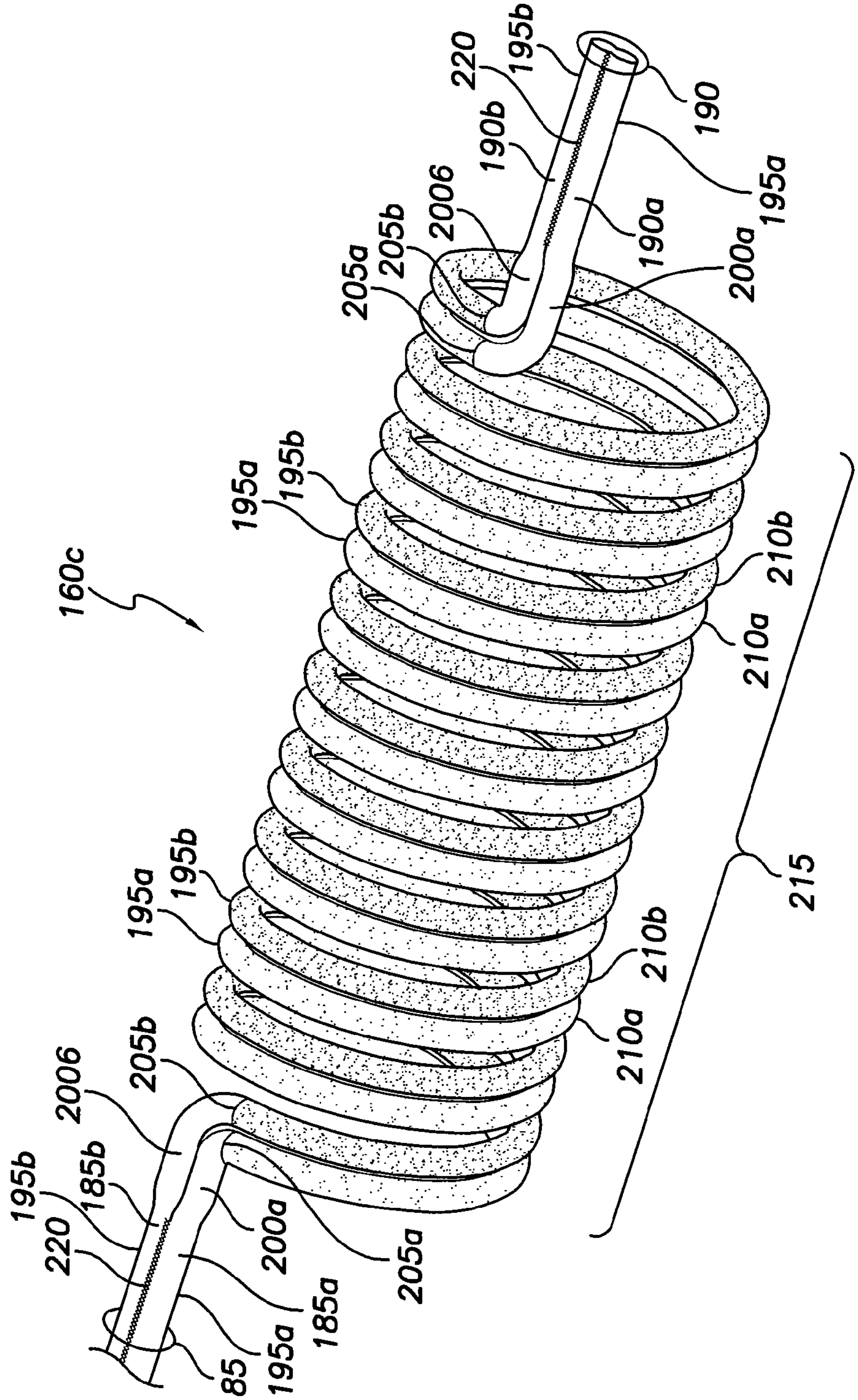
185a
195a
185

FIG. 4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195a
2006
205b
205a
190a
200a
195a
195b
210b
210a
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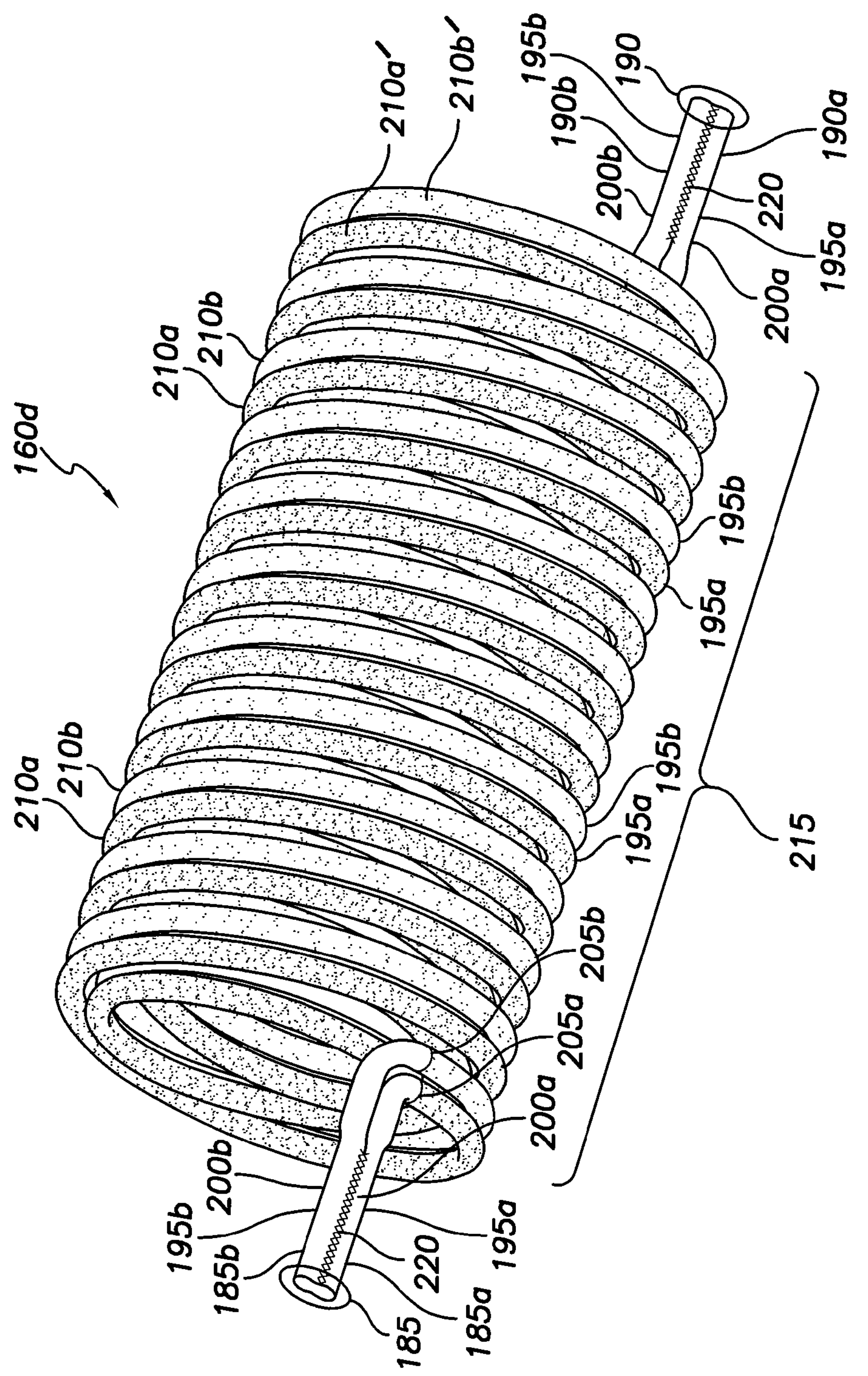
185a
195a
185

FIG. 5


160d
210a'
210b'
195b
190
190b
190a
200b
220
195a
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210b
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195a
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210b
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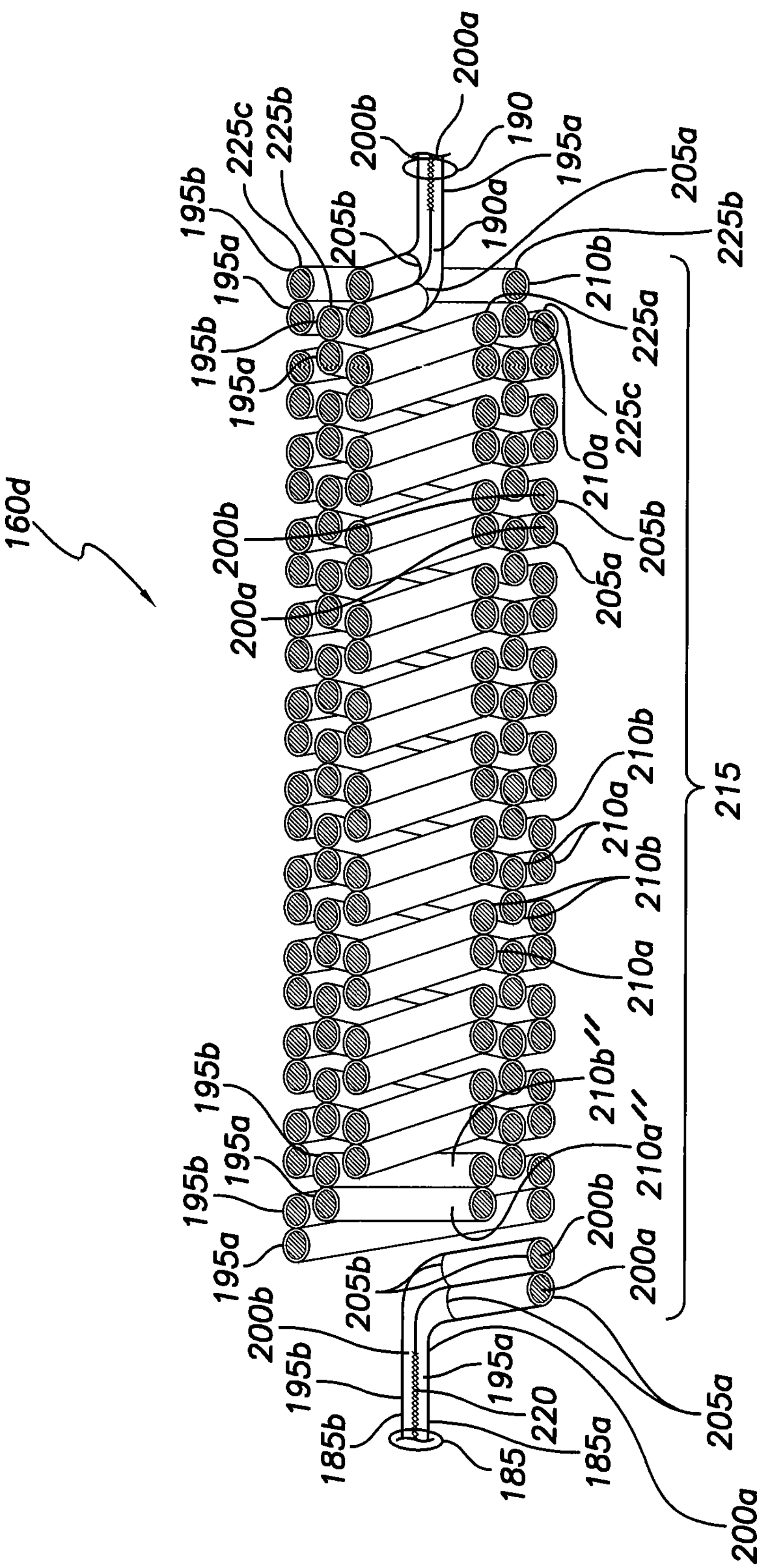
205a
200a
200b
195b
195a
220
185b
185a
185

FIG. 6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200b
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195a
190a
205a
205b
225b
225c
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210b
225a
210a
215
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210a''
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185b
185
220

FIG. 7

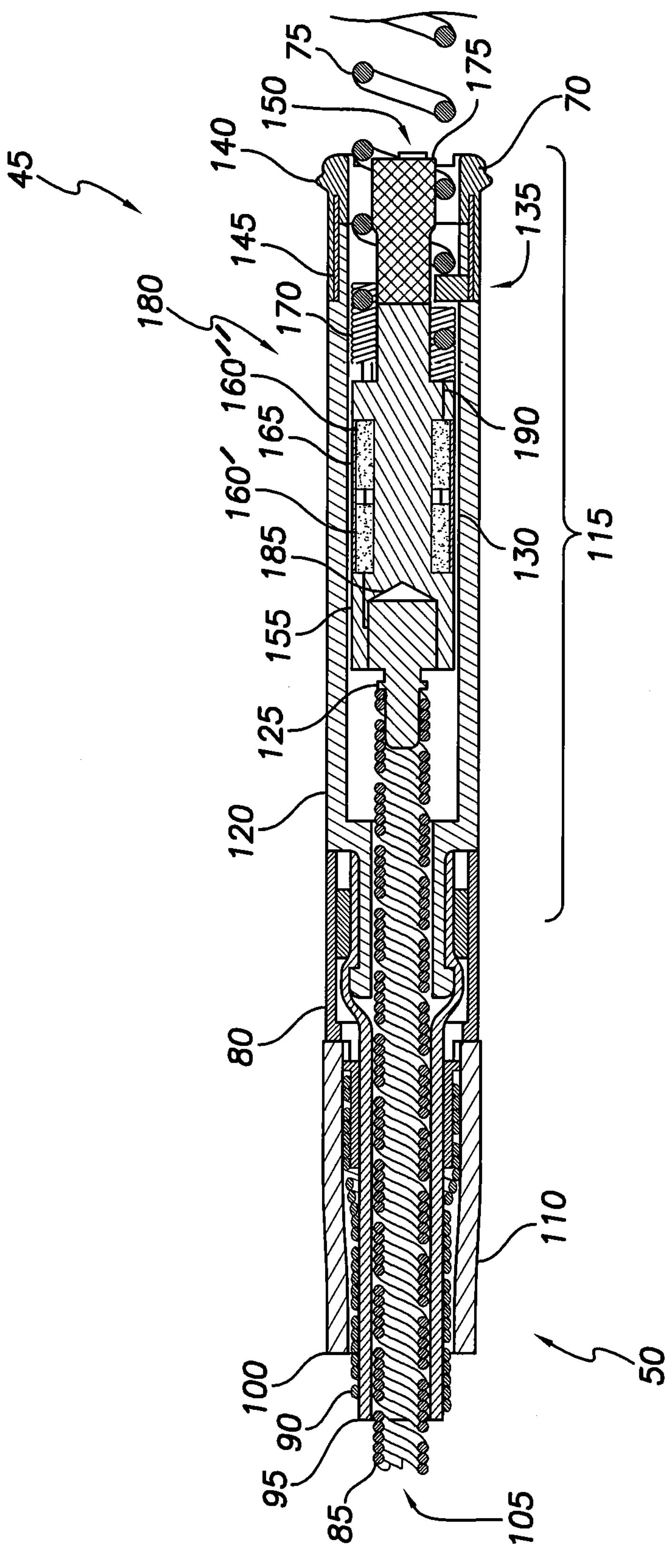
45
75
175
150
70
140
135
145
180
170
160''
190
165
160'
115
130
185
155
125
120
80
110
100
50
90
95
85
105

FIG. 8

MRI COMPATIBLE IMPLANTABLE MEDICAL LEAD AND METHOD OF MAKING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to U.S. patent application Ser. No. 12/262,047, filed concurrently herewith on Oct. 30, 2008, titled "MRI Compatible Implantable Medical Lead and Method of Making Same", now U.S. Pat. No. 8,634,931.

FIELD OF THE INVENTION

The present invention relates to medical apparatus and methods. More specifically, the present invention relates to implantable medical leads and methods of manufacturing such leads.

BACKGROUND OF THE INVENTION

Existing implantable medical leads for use with implantable pulse generators, such as neurostimulators, pacemakers, defibrillators or implantable cardioverter defibrillators ("ICD"), are prone to heating and induced current when placed in the strong magnetic (static, gradient and RF) fields of a magnetic resonance imaging ("MRI") machine. The heating and induced current are the result of the lead acting like an antenna in the magnetic fields generated during a MRI. Heating and induced current in the lead may result in deterioration of stimulation thresholds or, in the context of a cardiac lead, even increase the risk of cardiac tissue damage and perforation.

Over fifty percent of patients with an implantable pulse generator and implanted lead require, or can benefit from, a MRI in the diagnosis or treatment of a medical condition. MRI modality allows for flow visualization, characterization of vulnerable plaque, non-invasive angiography, assessment of ischemia and tissue perfusion, and a host of other applications. The diagnosis and treatment options enhanced by MRI are only going to grow over time. For example, MRI has been proposed as a visualization mechanism for lead implantation procedures.

There is a need in the art for an implantable medical lead configured for improved MRI safety. There is also a need in the art for methods of manufacturing and using such a lead.

BRIEF SUMMARY OF THE INVENTION

An implantable medical lead is disclosed herein. In one embodiment, the lead includes a body and an electrical pathway. The body may include a distal portion with an electrode and a proximal portion with a lead connector end. The electrical pathway may extend between the electrode and lead connector end and may include a coiled inductor including first and second electrically conductive filar cores. The first and second filar cores may be physically joined into a unified single piece proximal terminal on a proximal end of the coiled inductor. The first and second cores may be physically joined into a unified single piece distal terminal on a distal end of the coiled inductor. The first and second filar cores may be helically wound into a coiled portion between the proximal and distal terminals, the filar cores being electrically isolated from each other in the coiled portion. The proximal terminal may be electrically coupled to a portion of the electrical pathway extending to the lead connector end, and the distal terminal may be electrically coupled to a portion of the electrical pathway extending to the electrode.

An implantable medical lead is disclosed herein. In one embodiment, the lead may include a lead body, an electrical pathway, and a coiled inductor. The lead body may include an electrode at a distal portion of the lead body and a lead connector end at a proximal portion of the lead body. The electrical pathway may extend between the electrode and the lead connector end. The coiled inductor may form a segment of the electrical pathway and may be formed of multiple filars helically wound to form a coiled portion of the coiled inductor. The multiple filars may be electrically insulated from each other along the coiled portion and physically electrically contacting at proximal and distal ends of the multiple filars.

While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following Detailed Description, which shows and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of an implantable medical lead and a pulse generator for connection thereto.

FIG. **2** is a longitudinal cross-section of the lead distal end.

FIG. **3** is an isometric view of a uni-filar single layer coil inductor.

FIG. **4** is an isometric view of a bi-filar single layer coil inductor having only one of its pair of filars provided with an electrically insulating jacket.

FIG. **5** is an isometric view of a bi-filar single layer coil inductor having both of its filars provided with electrically insulating jackets.

FIG. **6** is an isometric view of a bi-filar multi-layer coil inductor.

FIG. **7** is a longitudinal cross-section of the coil inductor of FIG. **6**.

FIG. **8** is the same view as FIG. **2**, except of an inductor assembly may employ two or more lumped inductors in electrically connected in series.

DETAILED DESCRIPTION

Disclosed herein is an implantable medical lead **10** employing a lumped inductor **160** near the distal end **45** of the lead **10**. In one embodiment, the lumped inductor **160** is a coil inductor **160** that may be a uni-filar single layer coil inductor **160***a*. To provide advantages not offered by the uni-filar single layer coil inductor **160***a*, the lumped inductor **160** is a coil inductor **160** that may be bi-filar single layer coil inductor **160***b*, **160***c* or a bi-filar multi-layer coil inductor **160***d*. The advantages provided by the bi-filar single layer coil inductor **160***b*, **160***c* and the bi-filar multi-layer coil inductor **160***d* include, among others, reduced DC resistance, increased heat conduction efficiency, circuit redundancy, large inductance at common MRI operating frequencies, and small size allowing the coil conductor **160** to be employed in 6F or smaller leads.

For a general discussion of an embodiment of a lead **10** employing the coil inductor **160**, reference is made to FIG. **1**, which is an isometric view of the implantable medical lead **10** and a pulse generator **15** for connection thereto. The pulse generator **15** may be a pacemaker, defibrillator, ICD or neurostimulator. As indicated in FIG. **1**, the pulse generator **15** may include a can **20**, which may house the electrical components of the pulse generator **15**, and a header **25**. The header may be mounted on the can **20** and may be configured to receive a lead connector end **35** in a lead receiving receptacle **30**.

As shown in FIG. **1**, in one embodiment, the lead **10** may include a proximal end **40**, a distal end **45** and a tubular body **50** extending between the proximal and distal ends. In some embodiments, the lead may be a 6 French, model 1688T lead, as manufactured by St. Jude Medical of St. Paul, Minn. In other embodiments, the lead may be a 6 French model 1346T lead, as manufactured by St. Jude Medical of St. Paul, Minn. In other embodiments, the lead **10** may be of other sizes and models. The lead **10** may be configured for a variety of uses. For example, the lead **10** may be a RA lead, RV lead, LV Brady lead, RV Tachy lead, intrapericardial lead, etc.

As indicated in FIG. **1**, the proximal end **40** may include a lead connector end **35** including a pin contact **55**, a first ring contact **60**, a second ring contact **61**, which is optional, and sets of spaced-apart radially projecting seals **65**. In some embodiments, the lead connector end **35** may include the same or different seals and may include a greater or lesser number of contacts. The lead connector end **35** may be received in a lead receiving receptacle **30** of the pulse generator **15** such that the seals **65** prevent the ingress of bodily fluids into the respective receptacle **30** and the contacts **55**, **60**, **61** electrically contact corresponding electrical terminals within the respective receptacle **30**.

As illustrated in FIG. **1**, in one embodiment, the lead distal end **45** may include a distal tip **70**, a tip electrode **75** and a ring electrode **80**. In some embodiments, the lead body **50** is configured to facilitate passive fixation and/or the lead distal end **45** includes features that facilitate passive fixation. In such embodiments, the tip electrode **75** may be in the form of a ring or domed cap and may form the distal tip **70** of the lead body **50**.

As shown in FIG. **2**, which is a longitudinal cross-section of the lead distal end **45**, in some embodiments, the tip electrode **75** may be in the form of a helical anchor **75** that is extendable from within the distal tip **70** for active fixation and serving as a tip electrode **75**.

As shown in FIG. **1**, in some embodiments, the distal end **45** may include a defibrillation coil **82** about the outer circumference of the lead body **50**. The defibrillation coil **82** may be located proximal of the ring electrode **70**.

The ring electrode **80** may extend about the outer circumference of the lead body **50**, proximal of the distal tip **70**. In other embodiments, the distal end **45** may include a greater or lesser number of electrodes **75**, **80** in different or similar configurations.

As can be understood from FIGS. **1** and **2**, in one embodiment, the tip electrode **75** may be in electrical communication with the pin contact **55** via a first electrical conductor **85**, and the ring electrode **80** may be in electrical communication with the first ring contact **60** via a second electrical conductor **90**. In some embodiments, the defibrillation coil **82** may be in electrical communication with the second ring contact **61** via a third electrical conductor. In yet other embodiments, other lead components (e.g., additional ring electrodes, various types of sensors, etc.) (not shown) mounted on the lead body distal region **45** or other locations on the lead body **50** may be in electrical communication with a third ring contact (not shown) similar to the second ring contact **61** via a fourth electrical conductor (not shown). Depending on the embodiment, any one or more of the conductors **85**, **90** may be a multi-strand or multi-filar cable or a single solid wire conductor run singly or grouped, for example in a pair.

As shown in FIG. **2**, in one embodiment, the lead body **50** proximal of the ring electrode **80** may have a concentric layer configuration and may be formed at least in part by inner and outer helical coil conductors **85**, **90**, an inner tubing **95**, and an outer tubing **100**. The helical coil conductor **85**, **90**, the inner tubing **95** and the outer tubing **100** form concentric layers of the lead body **50**. The inner helical coil conductor **85** forms the inner most layer of the lead body **50** and defines a central lumen **105** for receiving a stylet or guidewire therethrough. The inner helical coil conductor **85** is surrounded by the inner tubing **95** and forms the second most inner layer of the lead body **50**. The outer helical coil conductor **90** surrounds the inner tubing **95** and forms the third most inner layer of the lead body **50**. The outer tubing **100** surrounds the outer helical coil conductor **90** and forms the outer most layer of the lead body **50**.

In one embodiment, the inner tubing **95** may be formed of an electrical insulation material such as, for example, ethylene tetrafluoroethylene ("ETFE"), polytetrafluoroethylene ("PTFE"), silicone rubber, silicone rubber polyurethane copolymer ("SPC"), or etc. The inner tubing **95** may serve to electrically isolate the inner conductor **85** from the outer conductor **90**. The outer tubing **100** may be formed of a biocompatible electrical insulation material such as, for example, silicone rubber, silicone rubber-polyurethane-copolymer ("SPC"), polyurethane, gore, or etc. The outer tubing **100** may serve as the jacket **100** of the lead body **50**, defining the outer circumferential surface **110** of the lead body **50**.

As illustrated in FIG. **2**, in one embodiment, the lead body **50** in the vicinity of the ring electrode **80** transitions from the above-described concentric layer configuration to a header assembly **115**. For example, in one embodiment, the outer tubing **100** terminates at a proximal edge of the ring electrode **80**, the outer conductor **90** mechanically and electrically couples to a proximal end of the ring electrode **80**, the inner tubing **95** is sandwiched between the interior of the ring electrode **80** and an exterior of a proximal end portion of a body **120** of the header assembly **115**, and the inner conductor **85** extends distally past the ring electrode **80** to electrically and mechanically couple to components of the header assembly **115** as discussed below.

As depicted in FIG. **2**, in one embodiment, the header assembly **115** may include the body **120**, a coupler **125**, an inductor assembly **130**, and a helix assembly **135**. The header body **120** may be a tube forming the outer circumferential surface of the header assembly **115** and enclosing the components of the assembly **115**. The header body **120** may have a soft atraumatic distal tip **140** with a radiopaque marker **145** to facilitate the soft atraumatic distal tip **140** being visualized during fluoroscopy. The distal tip **140** may form the extreme distal end **70** of the lead **10** and includes a distal opening **150** through which the helical tip anchor **75** may be extended or retracted. The header body **120** may be formed of polyetheretherketone ("PEEK"), polyurethane, or etc., the soft distal tip **140** may be formed of silicone rubber, SPC, or etc., and the radiopaque marker **145** may be formed of platinum, platinum-iridium alloy, tungsten, tantalum, or etc.

As indicated in FIG. **2**, in one embodiment, the inductor assembly **130** may include a bobbin **155**, a coil inductor **160** and a shrink tube **165**. The bobbin **155** may include a proximal portion that receives the coupler **125**, a barrel portion about which the coil inductor **160** is wound, and a distal portion coupled to the helix assembly **135**. The bobbin **155** may be formed of an electrical insulation material such as PEEK, polyurethane, or etc.

As illustrated in FIG. **2**, the shrink tube **165** may extend about the coil inductor **160** to generally enclose the coil inductor **160** within the boundaries of the bobbin **155** and the shrink tube **165**. The shrink tube **165** may act as a barrier between the coil inductor **160** and the inner circumferential surface of the header body **120**. Also, the shrink tube **165** may be used to form at least part of a hermitic seal about the coil inductor **160**. The shrink tube **165** may be formed of fluorinated ethylene propylene ("FEP"), polyester, or etc.

As shown in FIG. **2**, a distal portion of the coupler **125** may be received in the proximal portion of the bobbin **155** such that the coupler **125** and bobbin **155** are mechanically coupled to each other. A proximal portion of the coupler **125** may be received in the lumen **105** of the inner coil conductor **85** at the extreme distal end of the inner coil conductor **85**, the inner coil conductor **85** and the coupler **125** being mechanically and electrically coupled to each other. The coupler **125** may be formed of MP35N, platinum, platinum iridium alloy, stainless steel, or etc.

As indicated in FIG. **2**, the helix assembly **135** may include a base **170**, the helical anchor electrode **75**, and a steroid plug **175**. The base **170** forms the proximal portion of the assembly **135**. The helical anchor electrode **75** forms the distal portion of the assembly **135**. The steroid plug **175** may be located within the volume defined by the helical coils of the helical anchor electrode **75**. The base **170** and the helical anchor electrode **75** are mechanically and electrically coupled together. The distal portion of the bobbin **155** may be received in the helix base **170** such that the bobbin **155** and the helix base **170** are mechanically coupled to each other. The base **170** of the helix assembly **135** may be formed of platinum, platinum-iridium alloy, MP35N, stainless steel, or etc. The helical anchor electrode **75** may be formed of platinum, platinum-iridium ally, MP35N, stainless steel, or etc.

As illustrated in FIG. **2**, a distal portion of the coupler **125** may be received in the proximal portion of the bobbin **155** such that the coupler **125** and bobbin **155** are mechanically coupled to each other. A proximal portion of the coupler **125** may be received in the lumen **105** of the inner coil conductor **85** at the extreme distal end of the inner coil conductor **85** such that the inner coil conductor **85** and the coupler **125** are both mechanically and electrically coupled to each other. The coupler **125** may be formed of MP35N, stainless steel, or etc.

As can be understood from FIG. **2** and the preceding discussion, the coupler **125**, inductor assembly **130**, and helix assembly **135** are mechanically coupled together such that these elements **125**, **130**, **135** of the header assembly **115** do not displace relative to each other. Instead these elements **125**, **130**, **135** of the header assembly **115** are capable of displacing as a unit relative to, and within, the body **120** when a stylet or similar tool is inserted through the lumen **105** to engage the coupler **125**. In other words, these elements **125**, **130**, **135** of the header assembly **115** form an electrode-inductor assembly **180**, which can be caused to displace relative to, and within, the header assembly body **120** when a stylet engages the proximal end of the coupler **125**. Specifically, the stylet is inserted into the lumen **105** to engage the coupler **125**, wherein rotation of the electrode-inductor assembly **180** via the stylet in a first direction causes the electrode-inductor assembly **180** to displace distally, and rotation of the electrode-inductor assembly **180** via the stylet in a second direction causes the electrode-inductor assembly **180** to retract into the header assembly body **120**. Thus, causing the electrode-inductor assembly **180** to rotate within the body **120** in a first direction causes the helical anchor electrode **75** to emanate from the tip opening **150** for screwing into tissue at the implant site. Conversely, causing the electrode-inductor assembly **180** to rotate within the body **120** in a second direction causes the helical anchor electrode **75** to retract into the tip opening **150** to unscrew the anchor **75** from the tissue at the implant site.

As already mentioned and indicated in FIG. **2**, the coil inductor **160** may be wound about the barrel portion of the bobbin **155**. A proximal end **185** of the coil inductor **160** may extend through the proximal portion of the bobbin **155** to electrically couple with the coupler **125**, and a distal end **190** of the coil inductor **160** may extend through the distal portion of the bobbin **155** to electrically couple to the helix base **170**. Thus, in one embodiment, the coil inductor **160** is in electrical communication with the both the inner coil conductor **85**, via the coupler **125**, and the helical anchor electrode **75**, via the helix base **170**. Therefore, the coil inductor **160** acts as an electrical pathway through the electrically insulating bobbin **155** between the coupler **125** and the helix base **170**. In one embodiment, all electricity destined for the helical anchor electrode **75** from the inner coil conductor **85** passes through the coil inductor **160** such that the inner coil conductor **85** and the electrode **75** both benefit from the presence of the coil inductor **160**, the coil inductor **160** acting as a lumped inductor **160** when the lead **10** is present in a magnetic field of a MRI.

As the helix base **170** may be formed of a mass of metal, the helix base **170** may serve as a relatively large heat sink for the inductor coil **160**, which is physically connected to the helix base **170**. Similarly, as the coupler **125** may be formed of a mass of metal, the coupler **125** may serve as a relatively large heat sink for the inductor coil **160**, which is physically connected to the coupler **125**.

The coil inductor **160** may have a variety of winding configurations. For example, as indicated in FIG. **3**, which is an isometric view of one example coil inductor configuration, the coil inductor **160** may be a uni-filar single layer coil inductor **160***a* formed of a helically wound single filar **195** having an electrically conductive core **200** and an electrical insulation layer **205**. The helically wound filar **195** forms a plurality of coils **210**, which form the coiled portion **215** of the coil inductor **160***a*. The coil **210** may define a center cylindrical space that receives the barrel portion of the bobbin **155** when the coil inductor **160***a* is wound about the barrel portion of the bobbin **155**, as indicated in FIG. **2**.

As illustrated in FIG. **3**, the helically wound filar **195** terminates on the proximal and distal ends of the coil inductor **160***a* as proximal and distal straight filar segments **185**, **190**, which extend through the respective proximal and distal portions of the bobbin **155** to respectively electrically couple to the coupler **125** and the helix base **170**, as discussed above with respect to FIG. **2**. The extent of the filar **195** extending through the coils **210** of the coiled portion **215** is jacketed by the electrical insulation layer **205**, and the extent of the filar **195** forming the proximal and distal straight segments **185**, **190** is un-insulated such that the electrically conductive core **200** is exposed.

The uni-filar single layer coil inductor **160***a* discussed above with respect to FIG. **3** may operate as a lumped inductor **160** for a lead **10** to reduce RF heating during a MRI scan. The uni-filar single layer coil inductor **160***a* may generate high impedance to resist induced RF current at selected high frequencies common to most MRI scans, such as, for example, 64 MHz for a 1.5 T MRI scanner and 128 MHz for a 3.0 T MRI scanner. The uni-filar single layer coil inductor **160***a* does not impact the pacing or sensing circuit in the lead **10** when the working frequency is less than approximately 1 KHz, resulting in a low-pass filter.

However, there are a number of shortcomings associated with the above-discussed uni-filar single layer coil inductor **160***a*. For example, the uni-filar construction of the coil inductor **160***a* does not provide pacing circuit redundancy, unlike the multi-filar coils or cables employed for the pacing conductors **85**, **90** of the lead **10**. Also, the uni-filar single layer coil inductor **160***a* results in a large DC resistance and poor heat conduction due to the singe filar **195**, which has a long route and a small diameter. Finally, to achieve a coil inductor **160** with the appropriate self resonant frequency ("SRF") for specific MRI frequencies, such as, for example, 64 MHz for a 1.5 T MRI scan, a uni-filar coil inductor should have five layers as opposed to a single layer, causing the coil inductor outside diameter to be larger than may be accommodated in a 6F lead.

To address the shortcomings associated with the above-discussed uni-filar single layer coil inductor **160***a* or a uni-filar multi-layer coil inductor, a lumped inductor **160** may be provided for the lead **10** wherein the lumped inductor **160** employs a multi-filar configuration similar to the single layer multi-filar coil inductors **160***b*, **160***c* discussed below with respect to FIGS. **4** and **5** or the multi-layer multi-filar coil inductor **160***d* discussed below with respect to FIGS. **6** and **7**.

As depicted in FIG. **4**, which is an isometric view of a multi-filar coil inductor configuration, the coil inductor **160** may be a bi-filar single layer coil inductor **160***b* formed of a pair of helically wound filars **195***a*, **195***b*. Each helically wound filar **195***a*, **195***b* has an electrically conductive core **200***a*, **200***b*. However, only one of the filars **195***a* has an electrical insulation layer **205**, the other filar **195***b* being completely free of an electrical insulation layer **205**.

As shown in FIG. **4**, the pair of helically wound filars **195***a*, **195***b* form a plurality of coils **210***a*, **210***b*, which form the coiled portion **215** of the coil inductor **160***b*. The coils **210***a*, **210***b* may define a center cylindrical space that receives the barrel portion of the bobbin **155** when the coil inductor **160***b* is wound about the barrel portion of the bobbin **155**, as indicated in FIG. **2**.

As illustrated in FIG. **4**, each helically wound filar **195***a*, **195***b* terminates on the proximal end of the coil inductor **160***b* as proximal straight filar segments **185***a*, **185***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece proximal straight filar segment **185**. Similarly, each helically wound filar **195***a*, **195***b* terminates on the distal end of the coil inductor **160***b* as distal straight filar segments **190***a*, **190***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece distal straight filar segment **190**. The unified single-piece proximal and distal straight filar segments **185**, **190** extend through the respective proximal and distal portions of the bobbin **155** to respectively electrically couple to the coupler **125** and the helix base **170**, as discussed above with respect to FIG. **2**.

As indicated in FIG. **4**, the extent of the insulated filar **195***a* extending through the coils **210***a* of the coiled portion **215** is jacketed by the electrical insulation layer **205**, and the extent of the insulated filar **195***a* forming the proximal and distal straight segments **185***a*, **190***a* is un-insulated such that the electrically conductive core **200***a* is exposed. The extent of the un-insulated filar **195***b* extending through the coils **210***b* of the coiled portion **215** is free of an electrical insulation layer **205** such that the electrically conductive core **200***b* is exposed, and the extent of the un-insulated filar **195***b* forming the proximal and distal straight segments **185***b*, **190***b* is un-insulated such that the electrically conductive core **200***b* is exposed. As the coils **210***a*, **210***b* of the insulated filar **195***a* and un-insulated filar **195***b* alternate with respect to position in the coiled inductor **160***b*, the insulation layer **205** of the insulated filar **195***a* electrically isolates the conductor core **200***a* of the insulated filar **195***a* from the conductor core **200***b* of the un-insulated filar **195***b* and the conductor core **200***b* of the un-insulated filar **195***b* from itself.

The preceding discussion regarding the multi-filar coil inductor **160***b* depicted in FIG. **4** was given in the context of the multi-filar coil inductor **160***b* being a bi-filar single layer coil inductor **160***b*. However, in some embodiments, the multi-filar coil inductor **160***b* of FIG. **4** may have three filars, four filars or more filars, the filars being helically wound, alternatingly located in the helical coil, joined at their respective proximal and distal straight filar segments, and every other filar being insulated, as discussed above.

FIG. **5** is an isometric view of another multi-filar coil inductor configuration similar to the multi-filar coil inductor **160***b* of FIG. **4**, except the bi-filar single layer coil inductor **160***c* of FIG. **5** has a pair of helically wound filars **195***a*, **195***b* that both have electrical insulation jackets **205***a*, **205***b*. As indicated in FIG. **5**, each helically wound filar **195***a*, **195***b* has an electrically conductive core **200***a*, **200***b* and an electrical insulation layer **205***a*, **205***b*.

As shown in FIG. **5**, the pair of helically wound filars **195***a*, **195***b* form a plurality of coils **210***a*, **210***b*, which form the coiled portion **215** of the coil inductor **160***c*. The coils **210***a*, **210***b* may define a center cylindrical space that receives the barrel portion of the bobbin **155** when the coil inductor **160***c* is wound about the barrel portion of the bobbin **155**, as indicated in FIG. **2**.

As illustrated in FIG. **5**, each helically wound filar **195***a*, **195***b* terminates on the proximal end of the coil inductor **160***c* as proximal straight filar segments **185***a*, **185***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece proximal straight filar segment **185**. Similarly, each helically wound filar **195***a*, **195***b* terminates on the distal end of the coil inductor **160***c* as distal straight filar segments **190***a*, **190***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece distal straight filar segment **190**. The unified single-piece proximal and distal straight filar segments **185**, **190** extend through the respective proximal and distal portions of the bobbin **155** to respectively electrically couple to the coupler **125** and the helix base **170**, as discussed above with respect to FIG. **2**.

As indicated in FIG. **5**, the respective extents of the insulated filars **195***a*, **195***b* extending through the respective coils **210***a*, **210***b* of the coiled portion **215** are jacketed by respective electrical insulation layers **205***a*, **205***b*, and the respective extents of the insulated filars **195***a*, **195***b* forming the respective proximal and distal straight segments **185***a*, **185***b*, **190***a*, **190***b* are un-insulated such that the respective electrically conductive cores **200***a*, **200***b* are exposed. The coils **210***a*, **210***b* of the insulated filars **195***a*, **195***b* alternate with respect to position in the coiled inductor **160***c*. The insulation layers **205***a*, **205***b* of the insulated filars **195***a*, **195***b* electrically isolate the conductor cores **200***a*, **200***b* from each other and from themselves.

The preceding discussion regarding the multi-filar coil inductor **160***c* depicted in FIG. **5** was given in the context of the multi-filar coil inductor **160***c* being a bi-filar single layer coil inductor **160***c*. However, in some embodiments, the multi-filar coil inductor **160***c* of FIG. **5** may have three filars, four filars or more filars, the filars being helically wound, alternatingly located in the helical coil, joined at their respective proximal and distal straight filar segments, and all insulated, as discussed above.

FIG. **6** is an isometric view of another multi-filar coil inductor configuration similar to the multi-filar coil inductor **160***c* of FIG. **5**, except the coil inductor **160** is a bi-filar multi-layer coil inductor **160***d*. FIG. **7** is a longitudinal cross-section of the coil inductor **160***d* of FIG. **6**. As indicated in FIGS. **6** and **7**, each helically wound filar **195***a*, **195***b* has an electrically conductive core **200***a*, **200***b* and an electrical insulation layer **205***a*, **205***b*. Also, the coil inductor **160***d* may have three layers **225***a*, **225***b*, **225***c*.

As shown in FIGS. **6** and **7**, the pair of helically wound filars **195***a*, **195***b* form a plurality of coils **210***a*, **210***b*, which form the coiled portion **215** of the coil inductor **160***d*. The coils **210***a*, **210***b* of the inner layer **225***a* may define a center cylindrical space that receives the barrel portion of the bobbin **155** when the coil inductor **160***d* is wound about the barrel portion of the bobbin **155**, as indicated in FIG. **2**.

As illustrated in FIGS. **6** and **7**, each helically wound filar **195***a*, **195***b* terminates on the proximal end of the coil inductor **160***d* as proximal straight filar segments **185***a*, **185***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece proximal straight filar segment **185**. Similarly, each helically wound filar **195***a*, **195***b* terminates on the distal end of the coil inductor **160***d* as distal straight filar segments **190***a*, **190***b*, which are joined together via joining material **220**, for example, a weld, solder, braze or electrically conductive epoxy, to form a unified single-piece distal straight filar segment **190**. The unified single-piece proximal and distal straight filar segments **185**, **190** extend through the respective proximal and distal portions of the bobbin **155** to respectively electrically couple to the coupler **125** and the helix base **170**, as discussed above with respect to FIG. **2**.

As indicated in FIGS. **6** and **7**, the respective extents of the insulated filars **195***a*, **195***b* extending through the respective coils **210***a*, **210***b* of the coiled portion **215** are jacketed by respective electrical insulation layers **205***a*, **205***b*, and the respective extents of the insulated filars **195***a*, **195***b* forming the respective proximal and distal straight segments **185***a*, **185***b*, **190***a*, **190***b* are un-insulated such that the respective electrically conductive cores **200***a*, **200***b* are exposed. The coils **210***a*, **210***b* of the insulated filars **195***a*, **195***b* alternate with respect to position in the coiled inductor **160***d*. The insulation layers **205***a*, **205***b* of the insulated filars **195***a*, **195***b* electrically isolate the conductor cores **200***a*, **200***b* from each other and from themselves.

As best understood from FIG. **7**, the three layers **225***a*, **225***b*, **225***c* of the coiled inductor **160***d* are wound in opposite pitch directions such that the inner and outer layers **225***a*, **225***c* are wound in a first pitch direction and the intermediate layer **225***b* is wound in a second opposite pitch direction. The coils **210***a*, **210***b* of the inner layer **225***a* are surrounded by the coils **210***a*, **210***b* of the intermediate layer **225***b*. The coils **210***a*, **210***b* of the intermediate layer **225***b* are surrounded by the coils **210***a*, **210***b* of the outer layer **225***c*. The coils **210***a*, **210***b* of the outer layer **225***c* are wound in a first pitch direction moving distally from the proximal straight filar segments **185***a*, **185***b* until reaching the distal end of the coiled portion **215**, where the coils **210***a*, **210***b* of the outer layer **225***c* transition into transition coils **210***a*', **210***b*' that extend into the intermediate layer **225***b* and have a generally neutral pitch. The coils **210***a*, **210***b* of the intermediate layer **225***b* are wound in a second pitch direction opposite the first pitch direction moving proximally from the transition coils **210***a*', **210***b*' until reaching the proximal end of the coiled portion **215**, where the coils **210***a*, **210***b* of the intermediate layer transition into transition coils **210***a*", **210***b*" that extend into the inner layer **225***a* and have a generally neutral pitch. The coils **210***a*, **210***b* of the inner layer **225***a* are wound in the first pitch direction moving distally from the transition coils **210***a*", **210***b*" until reaching the distal end of the coiled portion **215**, where the coils **210***a*, **210***b* of the inner layer **225***a* extend into the distal straight filar segments **190***a*, **190***b*.

The preceding discussion regarding the multi-filar multi-layer coil inductor **160***d* depicted in FIGS. **6** and **7** was given in the context of the multi-filar multi-layer coil inductor **160***d* being a bi-filar three-layer coil inductor **160***d*. However, in some embodiments, the multi-filar multi-layer coil inductor **160***d* of FIGS. **6-7** may have three filars, four filars or more filars. Also, instead of three layers **225***a*, **225***b*, **225***c*, the coil inductor **160***d* of FIGS. **6-7** may have two layers, four layers, five layer or more layers. Even with a different number of filars and/or layers, the coiled inductor **160***d* of FIGS. **6-7** may have filars helically wound, alternatingly located in the helical coil, joined at their respective proximal and distal straight filar segments, and all insulated, as discussed above.

In some embodiments to facilitate the multi-filar multi-layer coil inductor having a terminal **185**, **190** on each opposite end of the coil inductor, the coil inductor may have an odd number of layers, for example, three, five, seven, etc. layers. Such an odd-numbered multi-layer configuration avoids an even-numbered coil inductor configuration wherein both terminals **185**, **190** are on the same end of the coil inductor, thereby possibly requiring an increased lead diameter to route an additional conductor along the coil inductor from one of the terminals **190** to the tip electrode.

In one embodiment of a multi-filar multi-layer coil inductor that may be tuned for 1.5 T or 3.0 T, the coil inductor may have 60 turns for each pair of filars in a layer and three such layers. Thus, such a bi-filar coil inductor may have 180 turns for each bi-filar pair.

In one version of the bi-filar three-layer coil inductor **160***d* of FIGS. **6** and **7**, the coil inductor **160***d* employs 44 gage insulated filars **195***a*, **195***b*. The filars **195***a*, **195***b* may have electrically conductive cores **200***a*, **200***b* formed of, for example, drawn filled tubing ("DFT") wire with a higher percentage of silver for less direct current resistance ("DCR") and less stiffness, platinum wire, platinum iridium alloy wire, copper wire, etc. The insulation **205***a*, **205***b* may have a thickness of between approximately 0.0003" and 0.0005" and is formed of a material such as, for example, ETFE, PTFE, PFA, polyimide, polyurethane, etc. The resulting coiled inductor **160***b* may have dimensions that allow it to fit into a 6F lead header.

The embodiments discussed above with respect to FIGS. **4-7** provide a number of advantages over the embodiment discussed with respect to FIG. **3**. For example, the multi-filar coil inductor circuit offers redundancy that may approximate the redundancy offered by the rest of the pacing circuit. This redundancy greatly benefits the lead reliability for over the lead's 10-year service life and the external defibrillator shock survival.

Due to the increased conductor cross-section offered by the multi-filar coiled inductor **160***b*, **160***c*, **160***d* as compared to the uni-filar coiled inductor **160***a*, the multi-filar coiled inductor **160***b*, **160***c*, **160***d* offers lower DC resistance than the uni-filar coiled inductor **160***a*, resulting in less heat generation during the large current pulse 8 A-2 ms test or the external defib shock. Also, the multi-filar coiled inductor **160***b*, **160***c*, **160***d* increases the heat conduction efficiency during the large current pulse 8 A-2 ms test or the external defib shock, as compared to the uni-filar coiled inductor **160***a*. Also, when packaged inside the lead header, there is a helix base **170** at the distal side of the coiled inductor **160**, and a coupler **125** at the proximal side of the coiled inductor **160**. Both the helix base **170** and the coupler **125** are of metals, such as Pt/Ir, MP35N, and can act as large heat sinks for the coiled inductor **160**. The larger total cross section area of the wire metal at each terminal **185**, **190** of the multi-filar coiled conductor **160***b*, **160***c*, **160***d* combined with the reduced number of turns or shorter length for each filar may double or triple the thermal conduction as compared to the uni-filar coiled inductor **160***a*.

The SRF of a multi-filar coiled lumped inductor **160***b*, **160***c*, **160***d* is easier to adjust to desired working frequency than a uni-filar coiled lumped inductor **160***a*. The parasitic inductance of a coiled lumped inductor **160** resulting from the insulation coatings is one of the two factors that define the SRF. For a uni-filar coil inductor **160***a*, to achieve the desired SRF of approximately 64 MHz for a 1.5 T MRI scan, five coil layers are needed when employing 44 gage wire for the filar, resulting in a lead header of at least 7F. On the other hand, the lead header may be reduced down to 6F for a bi-filar three layer coil inductor **160***d* employing 44 gage wire for the filars, achieving the desired SRF of approximately 64 MHz for a 1.5 T MRI scan.

For the multi-filar coiled inductors **160***b*, **160***c*, **160***d*, the large inductance and the SRF near the working frequency of 64 MHz or 128 MHz generate high impedance at the MRI working frequency. This filters the induced RF current and minimizes the RF heating at the lead electrode, while not adversely impacting the pacing occurring via the lead.

The inductance of the multi-filar coiled inductors **160***b*, **160***c*, **160***d* is not adversely impacted by the increased filar number as compared to the uni-filar coiled inductor **160***a*. In some embodiments as can be understood from a comparison of FIGS. **3**-**5**, this is because the total number of coil turns are similar between the uni-filar and bi-filar coiled inductors **160***a*, **160***b*, **160***c*, and total number of coil turns may be one of the dominate factors for the inductance of a coiled inductor **160**.

For the multi-filar multi-layered coiled inductor **160***d*, the small diameter insulated filars and multi-layered tight winding can save space while increasing the total number of the coil turns. Also, the insulated filars and multi-layered tight winding can result in strong electromagnetic interactions or mutual inductance and capacitance due to the skin effects. The result of the multi-filar multi-layered coiled inductor **160***d* is a coiled inductor **160** that offers output inductance that is essentially the same as a uni-filar coiled inductor **160***a*, but in a package that is substantially smaller than the uni-filar coiled inductor.

For any one or more of the coil inductor configurations discussed above with respect to FIGS. **3**-**7** and as can be understood from FIG. **2**, the coil inductor **160** may have a coil inductor length ICL that extends between the proximal and distal extents of the coiled portion **215** of between approximately 0.02" and approximately 0.25". The coil inductor **160** may also have an coil inductor inner diameter ICID of between approximately 0.01" and approximately 0.05". The coil inductor **160** may also have an coil inductor outer diameter ICOD of between approximately 0.01" and approximately 0.125".

For any one or more of the coil inductor configurations discussed above with respect to FIGS. **3**-**7**, the insulation layer **205** may be formed of polymer materials such as, for example, ETFE, PTFE, perfluoroalkoxy copolymer resin ("PFA"), polyimide, polyurethane, or etc. The insulation layer **205** may also have a radial thickness of between approximately 0.0001" and approximately 0.003".

For any one or more of the coil inductor configurations discussed above with respect to FIGS. **3**-**7**, the conductive core **200** may be formed of an electrically conductive biocompatible material such as, for example, platinum, platinum-iridium alloy, MP35N, silver-cored MP35N, titanium, titanium alloy or etc. Alternatively, assuming adequate hermetic sealing of the coil inductor **160**, the conductive core **200** may be formed of an electrically conductive non-biocompatible material such as, for example, copper or etc. The conductive core **200** may have a diameter of between approximately 0.0005" and approximately 0.005".

For any one or more of the coil inductor configurations discussed above with respect to FIGS. **4**-**7**, the insulation **205***a* for the first filar **195***a* may be of a different material than the insulation **205***b* of the second filar **195***b*. For example, the insulation **205***a* for the first filar **195***a* may be of ETFE and the insulation **205***b* of the second filar **195***b* may be PTFE. Alternatively or additionally, the insulation **205***a* for the first filar **195***a* may be of a different thickness than the insulation **205***b* of the second filar **195***b*. For example, the insulation **205***a* for the first filar **195***a* may have a thickness of 0.001" and the insulation **205***b* of the second filar **195***b* may have a thickness of 0.002".

As can be understood from FIG. **8**, which is the same view as FIG. **2**, except of another embodiment, the inductor assembly **130** may employ two or more lumped inductors **160'**, **160"** in electrically connected in series. The two or more lumped inductors **160'**, **160"** in series may be in the form of two or more identical coiled inductors **160'**, **160"** in series and of any one of the coiled inductor configurations discussed above with respect to FIGS. **3**-**7**. Alternatively, the two or more lumped inductors **160'**, **160"** in series may be in the form of two or more identical coiled inductors **160'**, **160"** in series and of any two or more of the coiled inductor configurations discussed above with respect to FIGS. **3**-**7**.

In one embodiment of the lead depicted in FIG. **8**, one inductor **160'** of the lumped inductors **160'**, **160"** in series is configured to be tuned for a first frequency such as, for example, 64 MHz for 1.5 T MRI scans, and the other inductor **160"** of the lumped inductors **160'**, **160"** in series is configured to be tuned for a second frequency such as, for example, 128 MHz for 3.0 T MRI scans.

In some embodiments, the inductors **160** may be other types of inductors besides coiled inductors. For example, in some embodiments, the inductors **160** may be printed circuit inductors, embedded circuit inductors, or multi-layer inductors. In some embodiments, a single inductor **160** may actually be formed of multiple types of inductors such as coil type inductors, multi-layer type inductors, embedded circuit inductors and printed circuit type inductors.

Although the present invention has been described with reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

1. An implantable medical lead comprising:

a body including a distal portion with an electrode and a proximal portion with a lead connector end; and

an electrical pathway extending between the electrode and lead connector end and including a single coiled inductor including first and second electrically conductive filar cores and a lead conductor electrically coupled between the lead connector end and the single coiled inductor, wherein the first and second filar cores are electrically coupled together at a proximal terminal on a proximal end of the coiled inductor, the first and second filar cores are electrically coupled together at a distal terminal on a distal end of the coiled inductor, and wherein the first and second filar cores are helically wound together into a coiled portion to form at least a portion of the single coiled inductor between the proximal and distal terminals, the filar cores being electrically isolated from each other in the coiled portion,

wherein the proximal terminal is located distal of the lead connector end and is electrically coupled to a distal end of the lead conductor, the lead conductor being electrically coupled to the lead connector end, and the distal terminal located proximal of the electrode is electrically coupled to a portion of the electrical pathway extending to the electrode.

2. The lead of claim **1**, wherein the first filar core is encased within an electrical insulation layer in the coiled portion and the second filar core is at least partially free of an electrical insulation layer in the coiled portion.

3. The lead of claim **1**, wherein the first filar core is encased within a first electrical insulation layer in the coiled portion and the second filar core is encased within a second electrical insulation layer in the coiled portion.

4. The lead of claim **3**, wherein a material of the first insulation layer is different from a material of the second insulation layer.

5. The lead of claim **3**, wherein a thickness of the first insulation layer is different from a thickness of the second insulation layer.

6. The lead of claim **3**, wherein the coiled portion includes multiple helical coil layers formed of the helically wound first and second filar cores.

7. The lead of claim **6**, wherein a first coil layer of the multiple helical coil layers is wound with a first pitch and a second coil layer of the multiple helical coil layers is wound with a second pitch opposite the first pitch.

8. The lead of claim **7**, wherein the second coil layer is immediately surrounding the first coil layer.

9. The lead of claim **1**, wherein the first and second filar cores in the coiled portion each form a series of respective coils and the coils of the first filar core and the coils of the second filar are arranged in an alternating fashion along a length of the coiled portion.

10. The lead of claim **1**, wherein the first and second cores are physically joined into a unified single piece distal and proximal terminals via at least one of welding, brazing, soldering, and electrically conductive epoxy.

11. The lead of claim **1**, further including a header assembly enclosing the coiled inductor.

12. An implantable medical lead comprising:

a lead body including an electrode at a distal portion of the lead body and a lead connector end at a proximal portion of the lead body;

an electrical pathway extending between the electrode and the lead connector end including a lead conductor forming a segment of the electrical pathway; and

a single coiled inductor forming a segment of the electrical pathway wherein the single coiled inductor is formed of multiple filars helically wound together to form at least a portion of a coiled portion of the single coiled inductor, wherein the multiple filars are electrically insulated from each other along the coiled portion and electrically coupled at proximal and distal ends of the multiple filars the proximal end of multiple filars being electrically coupled to a distal end of the lead conductor, the lead conductor being electrically coupled to a lead connector the distal end of the multiple filars being proximal of the electrode and being electrically coupled to the electrode.

13. The lead of claim **12**, wherein the multiple filars are helically wound in an alternating fashion so coils of a first helically wound filar of the multiple filars and coils of a second helically wound filar of the multiple filars are alternatingly located in the helical coil.

14. The lead of claim **12**, wherein at least one of the multiple filars is encased within an electrical insulation layer in the coiled portion and at least another one of the multiple filars is at least partially free of an electrical insulation layer in the coiled portion.

15. The lead of claim **12**, wherein all of the multiple filars are encased within an electrical insulation material.

16. The lead of claim **12**, wherein a material of a first insulation layer for at least one of the multiple filars is different from a material of a second insulation layer for another at least one of the multiple filars.

17. The lead of claim **12**, wherein a thickness of a first insulation layer for at least one of the multiple filars is different from a thickness of a second insulation layer for another at least one of the multiple filars.

18. The lead of claim **12**, wherein the multiple filars is at least one of 2, 3, 4, 5, and 6 filars.

19. The lead of claim **12**, wherein the multiple filars is at least two filars.

20. The lead of claim **12**, wherein the coiled portion includes multiple helical coil layers formed of the helically wound multiple filars.

21. The lead of claim **20**, wherein the multiple helical coil layers is at least one 2, 3, 4, 5 and 6 layers.

22. The lead of claim **20**, wherein the multiple helical coil layers is at least two layers.

23. The lead of claim **20**, wherein at least one of the multiple helical coil layers is wound with a first pitch and a second coil layer of the multiple helical coil layers is wound with a second pitch opposite the first pitch.

24. The lead of claim **23**, wherein the second coil layer is immediately surrounding the first coil layer.

25. The lead of claim **12**, wherein the proximal and distal ends of the multiple filars are physically joined into respective unified single piece distal and proximal terminals via at least one of welding, brazing, soldering, and electrically conductive epoxy.

26. The lead of claim **12**, wherein the coiled inductor includes a first inductor tuned for a first frequency and a second inductor tuned for a second frequency different from the first frequency.

27. The lead of claim **26**, wherein the first frequency is 64 MHz and the second frequency is 128 MHz.

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